K123671 1/2

Premarket Notification [510(k)] Summary

JAN 16 2013

Device details	Name Trade:	Wellaho Personalized Outpatient Management System
	Common name:	Telemedicine System
	Classification name:	Radiofrequency Physiological Signal Transmitter and Receiver
	Regulation number:	870.2910
	Product code:	DRG
	Classification panel:	Cardiovascular Devices
	Classification:	Class II device

Submitter: Sanitas, Inc.
1640 El Camino Del Teatro
La Jolla, CA 92037

Tel: 858-945-0660

Contact person: Mr. Naser Partovi, CEO

Intended Use

Wellaho Personalized Outpatient Management System is a software system that collects patient physiological data (such as blood pressure and blood sugar levels) for transmission to a secure central storage server, which can be accessed by health care professionals for analysis and intervention using standard digital communication technologies and protocols. These data are also available to the patient for viewing purposes and as an aid in maintaining wellness regimens.

Indication for Use

The Wellaho™ Personalized Outpatient Management System is an accessory software application that is used by patients in non-clinical settings (e.g. home), to collect, record and transmit their physiological information to a remote secure server. Stored data is accessible by healthcare professionals for analysis and intervention using standard digital communication technologies and protocols. The Wellaho is also intended to be used in combination with a variety of external vital sign devices. The Wellaho Personalized Outpatient Management System does not measure, interpret or make any decisions on the data that it conveys. It is not intended as a replacement for the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring.

Predicate Device Information:

The Wellaho Personalized Outpatient Management System is of comparable type and is

substantially equivalent to the following legally marketed predicate device:

Company	Device	510 (k)
Vignet Corporation	Vignet Tele-Health Manager	K113446

In further support of substantial equivalency, Section 12 provides a comparison table of the Wellaho Personalized Outpatient Management System and the predicate device.

The Wellaho Personalized Outpatient Management System is substantially equivalent (SE) to the predicate device, the Vignet Tele-Health Manager.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 16 2013

Sanitas, Inc
c/o Mr. Alan Donald, MS, MBA, FRAPS
11440 W. Bernardo Court Suite 300
San Diego, CA 92127

Re: K123671
Trade/Device Name: Wellaho Personalized Outpatient Management System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: November 28, 2012
Received: November 29, 2012

Dear Mr. Donald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Indications for Use Statement

510(k) Number: _____

Device Name: Wellaho™ Personalized Outpatient Management System

Indications For Use:

The Wellaho™ Personalized Outpatient Management System is an accessory software application that is used by patients in non-clinical settings (e.g. home), to collect, record and transmit their physiological information to a remote secure server. Stored data is accessible by healthcare professionals for analysis and intervention using standard digital communication technologies and protocols. The Wellaho is also intended to be used in combination with a variety of external vital sign devices. The Wellaho Personalized Outpatient Management System does not measure, interpret or make any decisions on the data that it conveys. It is not intended as a replacement for the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring.

Prescription

Prescription Use	AND/OR	Over-The-Counter Use XX
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123671